Drafting Biotechnology and Pharmaceutical Patent Claims

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Introduction

The drafting of biotechnology and pharmaceutical patent claims is informed by generic claim drafting principles that would apply in other fields of endeavor, such as mechanical and electrical claim drafting. Beyond these general prescriptions, however, exist the intricacies of technology-specific claim drafting that have evolved as a consequence of the claim interpretations applied by the USPTO and the federal courts in the administration and enforcement of biotechnology and pharmaceutical patent claims. As with all patent claims, the nature of the claims as a part of the patent specification requires a proper contextualization in determining the adequacy of definitional support of the claim language by the patent specification, including any figures. In this regard, the claim terms may not be properly examined in the abstract or by isolated reference, but instead require resort to the remainder of the intrinsic evidence (namely, the claims, the written description, and the prosecution history) to effectuate an appropriate construction of the meaning and scope of the patent claim as a whole.

With biotechnology and pharmaceutical patent claims in particular, a proper claim interpretation depends upon the sufficiency of the supporting disclosure in the patent specification as measured by the compliance with the requirements of 35 U.S.C. § 112 in written description, enablement, best mode, and definiteness. Still, it remains instructive to set forth strategies for claiming biotechnology and pharmaceutical subject matter with the recognition that the success of such strategies in any specific prosecution will depend on the facts of that case.

Applicable Patent Law Principles

An issued U.S. patent is entitled to a statutory presumption of validity under 35 U.S.C. § 282 (1994). This presumption, however, may be overcome where clear and convincing evidence exists that the USPTO erred in granting the patent in view of the cited prior art, or reached the incorrect conclusion because of the absence of other material information.[1] Patent invalidity may rest upon grounds that the claimed invention is not useful, novel or nonobvious under 35 U.S.C. §§ 101-103. In addition, patent invalidity may arise from failure to satisfy the statutory disclosure requirements under 35 U.S.C. § 112. Accordingly, the compliance with these statutory requirements forms the basis for patent claims that will survive challenge in the district courts upon enforcement.

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[1] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1375 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

In patent enforcement proceedings, the court must render an interpretation of the patent claims that seeks to preserve, rather than defeat, their validity.[2] In addition, the court must adopt the same claim construction for both its validity analysis and infringement determination.[3] In view of the proper claim interpretation, a court may assess the following in determining the validity of a U.S. patent:[4]

1. Statutory Subject Matter. To receive patent protection, the invention must qualify as appropriate subject matter, which can include a rather broad range of inventions.[5] Whether an invention constitutes patentable subject matter is a matter of statutory construction, which the Federal Circuit reviews de novo.[6]

2. Utility. To receive patent protection, the invention must have utility and must be capable of being used to effect the object proposed.[7] Whether an invention claimed

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[2] *C.R. Bard, Inc. v. M3 Sys.*, 157 F.3d 1340, 1363 (Fed. Cir. 1998).

[3] *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1556 (Fed. Cir. 1997).

[4] Various reviews of judicial decisions in cases involving invalidity challenges to U.S. patents report that the courts have historically held the patents-in-suit invalid in about 45% of such cases. *See, e.g.*, Donald R. Dunner, *The United States Court of Appeals for the Federal Circuit: Its First Three Years*, 13 AM. INTELL. PROP. L. ASS'N Q.J. 185, 186-87 (1985); Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AM. INTELL. PROP. L. ASS'N Q.J. 369, 420 (1994); Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 803, 822 (1988). Another review explored the relative percentage of patent invalidity holdings based on particular grounds. *See* John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTELL. PROP. L. ASS'N Q.J. 185, 209 (1998).

[5] *See Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("[Patentable subject matter includes anything under the sun that is made by man."); *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001) (newly developed plant breeds); *State Street Bank & Trust Co. v. Signature Fin. Group, Inc*., 149 F.3d 1368, 47 USPQ2d 1596 (Fed. Cir. 1998) (business methods). *But see Bilski v. Kappos*, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010) ("[T]he machine-or-transformation test [i.e., holding that an invention is a "process" only if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing"] is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible "process.").

[6] *See State Street*, 149 F.3d at 1370, 47 USPQ2d at 1598.

[7] *See Brenner v. Manson*, 383 U.S. 519, 534 (1966); *Cross v. Iizuka*, 753 F.2d 1040, 1044 (Fed. Cir. 1985); *see also* In re *Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

in a patent lacks utility is a question of fact, which the U.S. Court of Appeals for the Federal Circuit reviews for clear error.[8]

3. Novelty. To receive patent protection, the invention must be novel, *i.e.*, not anticipated by the prior art.[9] An invention is anticipated if a single prior art reference expressly or inherently discloses each and every limitation of the claimed invention.[10] A

[8] *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983). In 20% of the cases involving an affirmative defense of patent invalidity for lack of utility, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[9] *See* 35 U.S.C. § 102(a)-(b). Under U.S. patent law, various events can also trigger the loss of the patent right. For example, the patent law bars patent protection of an invention that was in public use or on sale more than one year before the filing date of the United States patent application for that invention. These patentability bars seek to encourage prompt disclosure of inventions to the public and the discouragement of commercial exploitation of the invention while deferring the start of the patent protection term.

A party asserting patent invalidity based on public use must prove by clear and convincing evidence that the invention was used before the critical date, in public, and primarily for purposes other than experimentation. *See Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1266 (Fed. Cir. 1986). Factors relevant to a public use inquiry include public access to and awareness of the activity, the degree of confidentiality imposed on observers, indicia of bona fide experimentation, and the financial aspects of the activity. *See Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564 (Fed. Cir. 1987). The Federal Circuit reviews *de novo* the district court's ultimate conclusion of public use, and reviews for clear error the underlying factual findings. *See Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 549 (Fed. Cir. 1990).

A party asserting patent invalidity based on on sale activity must prove by clear and convincing evidence that a definite sale or offer to sell occurred before the critical date and that the subject matter of the sale or offer to sell either anticipated the claimed invention or would have rendered the claimed invention obvious. *See UMC Elecs. Co. v. United States*, 816 F.2d 647, 656 (Fed. Cir. 1987). The Federal Circuit reviews *de novo* the district court's ultimate conclusion of on sale activity and reviews for clear error the underlying factual findings. *See Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834, 836 (Fed. Cir. 1992).

[10] *See Scripps Clinic & Research Found. v. Genentech Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991).

party must prove anticipation by clear and convincing evidence.[11] Anticipation is a question of fact that the Federal Circuit reviews for clear error.[12]

4. Nonobviousness. To receive patent protection, an invention must be nonobvious at the time of the invention to one of ordinary skill in the relevant art.[13] An accused infringer must prove obviousness by clear and convincing evidence.[14] Obviousness is a question of law that the Federal Circuit reviews *de novo*.[15] The conclusion of obviousness is subject to underlying factual findings, however.[16] These findings include the scope and content of the prior art, the level of ordinary skill in the art at the time of the invention, objective evidence of nonobviousness, and differences between the prior art and the claimed invention. Relevant secondary considerations of non-obviousness include commercial success, long felt but unsolved needs, failures of others, and copying. The Federal Circuit reviews the factual findings of the district court for clear error.[17]

5. Written Description. To obtain patent protection, an inventor must set forth an adequate written description of the invention.[18] This statutory requirement ensures that the subject matter of a claim presented after the filing date of the patent application was sufficiently disclosed at the time of filing so that the prima facie date of invention can fairly be held to be the filing date of the application.[19] This issue arises, for example, out of an assertion of entitlement to the filing date of a previously filed application under 35 U.S.C. § 120.[20] The adequacy of a written description is a question

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[11] *See Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 632 (Fed. Cir. 1987). In 40.7% of the cases involving an affirmative defense of patent invalidity for anticipation, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[12] *See Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 619 (Fed. Cir. 1985).

[13] 35 U.S.C. § 103 (2004); *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

[14] *See Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1558 (Fed. Cir. 1986). In 36.3% of the cases involving an affirmative defense of patent invalidity for obviousness, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[15] *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1182 (Fed. Cir. 1991).

[16] *See Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

[17] *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1565-66 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987).

[18] *See* 35 U.S.C. § 112, ¶ 1 (2004).

[19] *See Hyatt v. Boone*, 146 F.3d 1348, 1354-55 (Fed. Cir. 1998); *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991); *In re Smith*, 481 F.2d 910, 914 (CCPA 1973).

[20] *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997).

of fact that the Federal Circuit reviews for substantial evidence to support the jury's verdict[21] or otherwise for clear error.[22]

6. Definiteness. To obtain patent protection, an inventor must set forth a claim that reasonably apprises those of skill in the art of its scope.[23] Whether a claim is invalid as indefinite depends upon whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.[24] Indefiniteness is a legal conclusion that the Federal Circuit reviews *de novo*.[25]

7. Enablement. In addition, an inventor must provide a disclosure sufficient to enable any person skilled in the art to practice the invention.[26] The specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.[27] A party must prove a lack of enablement by clear and convincing evidence.[28] Enablement is a question of law that

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[21] *See Wang Lab., Inc. v. Toshiba Corp.*, 993 F.2d 858, 865 (Fed. Cir. 1993). In 36.1% of the cases involving an affirmative defense of patent invalidity for inadequate written description, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[22] *See Vas-Cath*, 935 F.2d at 1563; *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989); *Utter v. Hiraga*, 845 F.2d 993, 998 (Fed. Cir. 1988); *Ralston Purina Co. v. Far-Mar-Co.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985).

[23] *See* 35 U.S.C. § 112, ¶ 2 (2004) (requiring that the patent "particularly [point] out and distinctly [claim] the subject matter which the applicant regards as his invention.").

[24] *See Orthokinetics Inc. v. Safety Travel Chairs Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986).

[25] *See N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1579 (Fed. Cir. 1993); *Renishaw*, 945 F.2d at 1181. In 34.8% of the cases involving an affirmative defense of patent invalidity for indefiniteness, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[26] *See Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

[27] *See Hybritech*, 802 F.2d at 1384.

[28] *See Morton Int'l Co. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1469 (Fed. Cir. 1993). In 36.1% of the cases involving an affirmative defense of patent invalidity for obviousness, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

the Federal Circuit reviews *de novo*.[29] The court reviews for clear error any underlying facts to the enablement conclusion.[30]

8. Best Mode. To obtain patent protection, an inventor must disclose the best mode personally known at the time of filing the application.[31] The best mode inquiry thus focuses on the inventor's state of mind based on personal knowledge of available facts.[32] A party must prove a best mode violation by clear and convincing evidence.[33] Compliance with the best mode requirement is a factual question that the Federal Circuit reviews for substantial evidence to support the jury's verdict[34] or otherwise for clear error.[35]

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[29] *See PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1564 (Fed. Cir. 1996); *In re Wands*, 858 F.2d 731, 735, 736-37 (Fed. Cir. 1988); *Moleculon*, 793 F.2d at 1268; *Quaker City Gear Works, Inc. v. Skil Corp.*, 747 F.2d 1446, 1453-54 (Fed. Cir. 1984).

[30] *See Gould v. Quigg*, 822 F.2d 1074, 1077 (Fed. Cir. 1987).

[31] *See* 35 U.S.C. § 112, ¶ 1 (requiring that the patent specification "set forth the best mode contemplated by the inventor of carrying out his invention").

[32] *See Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927 (Fed. Cir. 1990) (stating that the fact-finder must consider not only the inventor's state of mind at the time the application is filed, but also the level of skill in art and the scope of the claimed invention); *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1535 (Fed. Cir. 1987) (noting that there is no clear objective standard to judge the adequacy of the best mode disclosure, but that evidence of accidental or intentional concealment is considered); *Hybritech*, 802 F.2d at 1384-85.

[33] *See Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 560 (Fed. Cir. 1994); *R.R. Dynamics, Inc. v. A. Stucki Co.*, 727 F.2d 1506, 1517 (Fed. Cir. 1984). In 35.6% of the cases involving an affirmative defense of patent invalidity for failure to disclose the best mode, the courts held the patent-in-suit invalid. *See* Allison, *supra* note 4, at 209.

[34] *See Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d 1543, 1550 (Fed. Cir. 1997); *Wang Labs. Inc. v. Mitsubishi Elecs. Am. Inc.*, 103 F.3d 1571, 1583 (Fed. Cir. 1997); *Great N. Corp. v. Henry Molded Prods. Inc.*, 94 F.3d 1569, 1572 (Fed. Cir. 1996); *Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 994 (Fed. Cir. 1995); *In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1536 (Fed. Cir. 1992); *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1546 (Fed. Cir. 1992).

[35] *See Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991); *Spectra-Physics, Inc. v. Coherent, Inc*., 827 F.2d 1524, 1535-36 (Fed. Cir. 1987); *DeGeorge v. Bernier*, 768 F.2d 1318, 1324 (Fed. Cir. 1985); *Coleman v. Dines*, 754 F.2d 353, 356 (Fed. Cir. 1985); *McGill, Inc. v. John Zink Co.*, 736 F.2d 666, 676 (Fed. Cir. 1984).

In addition, a court can consider whether a U.S. patent may be unenforceable due to inequitable conduct. Patent applicants and their representatives have a duty of candor, good faith, and honesty in their dealings with the USPTO.[36] Breach of this duty constitutes inequitable conduct.[37] A party alleging inequitable conduct must prove by clear and convincing evidence that the patent applicant intentionally misrepresented or withheld material information from the patent examiner.[38] Information is material if a substantial likelihood exists that a reasonable examiner would have considered it necessary to a proper patentability assessment of an invention.[39] Circumstantial evidence may allow the inference of an intent to deceive the USPTO.[40] Evidence of gross negligence alone, however, cannot support a finding of deceptive intent.[41]

The Federal Circuit reviews for abuse of discretion the district court's determination of inequitable conduct.[42] Misrepresentation, materiality, and intent to deceive are underlying questions of fact that the Federal Circuit reviews for clear error.[43]

Accordingly, the validity and enforceability of a U.S. patent entails the determination whether the patent claims meet the statutory conditions of patentability, which requires a comparison of the properly construed claims against the prior art. Similarly, the determination whether the patent claims meet the statutory disclosure

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[36] *See Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 818 (1945) (stating that persons with pending applications at Patent Office have an "uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue").

[37] *See id.* (explaining that only through requiring disclosure can the USPTO prevent inequitable conduct, thereby protecting the public from "fraudulent patent monopolies"); 37 C.F.R. § 1.56 (describing the intentional failure to report material information as inequitable conduct).

[38] *See Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1556-57 (Fed. Cir. 1995); *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867, 872 (Fed. Cir. 1988).

[39] *See* 37 C.F.R. § 1.56 (delineating duties to disclose information material to patentability).

[40] *See Paragon Podiatry Lab. v. KLM Lab. Inc.*, 984 F.2d 1182, 1189-90 (Fed. Cir. 1993); *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983) (stating the presumption that one intends the natural consequences of one's acts).

[41] *See Kingsdown*, 863 F.2d at 876 (noting that all evidence is necessary in determining the intent to deceive).

[42] *See Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1541 (Fed. Cir. 1997).

[43] *See Kingsdown*, 863 F.2d at 872.

requirements necessitates a comparison of the properly construed claims against the teachings of the patent. In either case, the initial consideration of the patent, its prosecution history, and the relevant prior art, to determine the proper scope of the patent claims is a prerequisite.[44]

Biotechnology and Pharmaceutical Patent Examination

In this field of endeavor, the issues of patentable subject matter and utility under 35 U.S.C. § 101, as well as written description and enablement under § 112 tend to come to the fore. The insufficiency of a distinction from naturally occurring products can be the basis for a nonstatutory subject matter rejection. In some instances, the lack of sufficient information regarding the biological significance or origin of a product also can implicate the patentability of claims drawn to that product and related processes because of a lack of utility and corresponding lack of enablement. The inability to provide adequate written description support for the breadth of the claims sought can also be problematic.

The USPTO has provided specific guidance with respect to utility and written description that is particularly relevant to biotechnology and pharmaceutical patent claims. *See* http://www.uspto.gov/web/menu/utility.pdf; http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf; and http://www.uspto.gov/web/offices/com/sol/notices/writdesguide.pdf. In addition, the USPTO issued updated patent examiner training materials on March 25, 2008, regarding compliance with the written description requirement. *See* http://www.uspto.gov/web/menu/written.pdf.

Under the utility guidelines, a patent examiner must read the claims and the supporting written description; determine what the applicant has claimed, noting any specific embodiments of the invention; and ensure that the claims define statutory subject matter (i.e., a process, machine, manufacture, composition of matter, or improvement thereof). If at any time during the examination, it becomes readily apparent that the claimed invention has a well-established utility, do not impose a rejection based on lack of utility. An invention has a well-established utility (1) if a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (2) the utility is specific, substantial, and credible.

In addition, the patent examiner must review the claims and the supporting written description to determine if the applicant has asserted for the claimed invention

[44] *Vitronics,* 90 F.3d at 1582.

any specific and substantial utility that is credible: (a) If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a ''specific and substantial utility'') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (1) A claimed invention must have a specific and substantial utility. This requirement excludes ''throw-away,'' ''insubstantial,'' or ''nonspecific'' utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement of 35 U.S.C. 101. (2) Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. (b) If no assertion of specific and substantial utility for the claimed invention made by the applicant is credible, and the claimed invention does not have a readily apparent well established utility, reject the claim(s) under § 101 on the grounds that the invention as claimed lacks utility. Also reject the claims under § 112, first paragraph, on the basis that the disclosure fails to teach how to use the invention as claimed. The § 112, first paragraph, rejection imposed in conjunction with a § 101 rejection should incorporate by reference the grounds of the corresponding § 101 rejection. (c) If the applicant has not asserted any specific and substantial utility for the claimed invention and it does not have a readily apparent well-established utility, impose a rejection under § 101, emphasizing that the applicant has not disclosed a specific and substantial utility for the invention. Also impose a separate rejection under § 112, first paragraph, on the basis that the applicant has not disclosed how to use the invention due to the lack of a specific and substantial utility. The §§ 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to: (1) Explicitly identify a specific and substantial utility for the claimed invention; and (2) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well established at the time of filing. The examiner should review any subsequently submitted evidence of utility using the criteria outlined above. The examiner should also ensure that there is an adequate nexus between the evidence and the properties of the now claimed subject matter as disclosed in the application as filed. That is, the applicant has the burden to establish a probative relation between the submitted evidence and the originally disclosed properties of the claimed invention.

Under the written description guidelines, the patent examiner must determine whether there is sufficient written description to inform a skilled artisan that the applicant was in possession of the claimed invention as a whole at the time the application was filed. Possession may be shown in many ways. For example, possession may be shown, inter alia, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in

detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. A specification may describe an actual reduction to practice by showing that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose. Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 C.F.R. § 1.801 et seq. An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is directed to a product or a process. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.

The new written description training materials provide seventeen examples, of which fourteen are specifically related to biotech inventions. In particular, the biotech-specific examples address expressed sequence tags (ESTs) (example 4), a partial protein structure (example 5), DNA hybridization (example 6), allelic variants (example 7), bioinformatics (example 8), protein variants (example 9), a product claimed by its function (example 10), a polynucleotide or polypeptide sequence sharing percent identity with another sequence (example 11), antisense oligonucleotides (example 12), antibodies to a single protein (example 13), antibodies to a genus of proteins (example 14), a genus with widely varying species (example 15), a process claim where novelty resides in the process steps (example 16), and methods of using compounds claimed by functional limitations, methods of identifying compounds, and compounds identified by such methods (example 17).

Representative Biotechnology and Pharmaceutical Patent Claims

This paper below presents various claims in issued U.S. patents as exemplars. However, the presentation of certain claims does not constitute a recommendation or otherwise indicate a favorable evaluation of those claims. Rather, these claims have been selected for particular training purposes.

U.S. Patent No. 7,402,664

1. An ***isolated polynucleotide*** sequence encoding a binding peptide having the amino acid sequence of SEQ ID NO:24, wherein said peptide binds to a carotenoid compound.

2. An expression ***vector*** comprising a polynucleotide encoding the phenol oxidizing enzyme-peptide complex comprising the amino acid sequence of SEQ ID NO:24.

3. A ***host cell*** comprising the vector of claim 2.

U.S. Patent No. 7,074,913

1. An ***isolated polynucleotide*** or complement thereof, the polynucleotide comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NO:2.

6. A ***vector*** comprising the polynucleotide of claim 1.

7. A vector comprising a ***non-native expression control sequence*** operably linked to a polynucleotide selected from the group consisting of the polynucleotide of claim 1 and a polynucleotide of claim 4.

9. A ***host cell*** comprising a non-native expression control sequence operably linked to a polynucleotide selected from the group consisting of the polynucleotide of claim 1 and a polynucleotide of claim 4.

11. A method for producing an anthrax toxin receptor, the method comprising the steps of: ***transcribing*** a polynucleotide operably linked to an upstream expression control sequence, wherein the polynucleotide is selected from the group consisting of the polynucleotide of claim 1 and a polynucleotide of claim 4 to produce an mRNA; and ***translating*** the mRNA to produce the anthrax toxin receptor.

U.S. Patent No. 7,067,636

1. An ***isolated antibody*** that specifically binds to the polypeptide of amino acid sequence set forth in SEQ ID NO:466.
2. The antibody of claim 1 which is a ***monoclonal antibody***.
3. The antibody of claim 1 which is a ***humanized antibody***.
4. The antibody of claim 1 which is an ***antibody fragment***.
5. The antibody of claim 1 which is ***labeled***.

U.S. Patent No. 7,070,935

1. A method for detecting one or more biological entities in a sample, comprising: (a) combining one or more nucleic acid sequences in a sample with multiple primers comprising randomized nucleotide sequences, said randomized sequences being sufficiently randomized such that substantially all of the nucleic acid sequences of a biological entity are represented among amplification products; (b) randomly ***amplifying*** the sample nucleic acid sequences to produce nucleic acid amplification products; (c) combining the amplification products with an ***array*** of predetermined nucleic acid sequences including redundancies which redundancies comprise multiple distinct nucleic acids from the same target entity and such that at least a portion of the amplification products hybridize to the array; and (d) detecting amplification products that hybridize to the array.

U.S. Patent No. 6,410,516

1. A method for inhibiting expression, in a eukaryotic cell, of a gene whose transcription is regulated by NF-κB, the method comprising ***reducing NF-κB activity*** in the cell such that expression of said gene is inhibited.

U.S. Patent No. 4,331,803

1. An ***erythromycin compound*** of the formula [X] wherein R^1 is hydrogen or methyl, and a pharmaceutically acceptable salt thereof.

U.S. Patent No. 5,547,933

4. A non-naturally occurring human erythropoietin glycoprotein possessing the in vivo biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells which is the **product of the process** comprising the steps of:

(a) growing, under suitable nutrient conditions, mammalian host cells transformed or transfected with an isolated DNA sequence encoding the human erythropoietin amino acid sequence set out in FIG. 6 or a fragment thereof; and

(b) isolating a glycosylated erythropoietin polypeptide therefrom.

U.S. Patent No. 6,551,616

1. A method of reducing gastrointestinal adverse side effects comprising administering an effective amount of an ***extended release pharmaceutical composition*** comprising an erythromycin derivative and a pharmaceutically acceptable polymer.

2. The method according to claim 1, wherein the erythromycin derivative is clarithromycin.

3. The method according to claim 2, wherein the composition comprises about 50% by weight of clarithromycin.

4. The method according to claim 3, wherein the composition comprises from about 10 to about 30% by weight of hydroxypropylmethylcellulose having a viscosity of about 100 cps.

U.S. Patent No. 7,052,834

1. A method for ***detecting*** inactivation of a CASP8 gene expression in a primary cancer cell, comprising detecting methylation of CASP8 genomic DNA.

6. A ***kit*** for detecting inactivation of a CASP8 gene expression, comprising oligonucleotide primer pairs for amplification of SEQ ID NO: 1 or SEQ ID NO: 2; wherein said primer pairs are oligonucleotides of at least 10 nucleotides that hybridize to SEQ ID NO: 1 or SEQ ID NO: 2 or to complete complements thereof, in a methylation polymerase chain reaction (PCR) assay for the detection of methylation of SEQ ID NO: 1 or SEQ ID NO: 2.

8. A method for ***prognosis*** of a neuroblastoma comprising detecting inactivation of a CASP8 gene expression in a neuroblastoma cell from a subject, wherein said inactivation of a CASP8 gene expression in the neuroblastoma cell is indicative of the inefficiency of apoptosis induced by activated death receptors, chemotherapeutic drugs, or irradiation, and wherein said method comprises detecting a methylation of CASP8 genomic DNA.

11. A method for ***diagnosis*** of an aggressive neuroblastoma comprising detecting inactivation of a CASP8 gene expression in a neuroblastoma cell from a subject, wherein said inactivation of a CASP8 gene expression in the neuroblastoma cell is indicative of the presence of an aggressive neuroblastoma and wherein said method comprises detecting a methylation of CASP8 genomic DNA.

Biography of the Author

Lawrence M. Sung holds an appointment as Law School Professor and Intellectual Property Law Program Director at the University of Maryland School of Law (Baltimore, MD), where he has taught since 2001 in courses including Biotechnology and Law: Ethical Issues, Intellectual Property Law Survey, Intellectual Property Aspects of Business Law, Licensing and Technology Transfer Law and Policy, and Patent Law and Policy. He has also taught at the George Washington University Law School, the American University, Washington College of Law, the Northwestern School of Law of Lewis & Clark College, and Seattle University School of Law.

He earned his B.A. in biology from the University of Pennsylvania, his Ph.D. in microbiology from the U.S. Department of Defense, Uniformed Services University, and his J.D. cum laude from the American University, Washington College of Law. Following graduation from law school, Professor Sung served as a judicial clerk to (now Senior) Circuit Judge Raymond C. Clevenger, III, U.S. Court of Appeals for the Federal Circuit (Washington, DC). A registered patent attorney, he entered private practice specializing in biotechnology patent litigation with several national law firms, and now as a Partner of the intellectual property law firm of Dewey & LeBoeuf LLP (Washington, DC).

He has testified before the U.S. House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property regarding gene patenting, and before the U.S. Department of Justice and Federal Trade Commission Joint Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy regarding biotechnology patent pools. He has published extensively in the area of intellectual property law on issues including those concerning biotechnology and technology transfer, and is the author of Patent Infringement Remedies (BNA Books 2004 & 2005-2010 Cumulative Supplements), The Patent Law Handbook (Thomson/West) 2003-2010 editions, and Medical Device Patents (Thomson/West) 2008-2010 editions.

He is also a former consultant to the National Human Genome Research Institute, Past Chairman of The National Research Council Committee on Intellectual Property Concerns for Toxicogenomics, Past Member of The National Academies Standing Committee on Emerging Issues and Data on Environmental Contaminants, Past Member of The National Research Council Committee on Validation of Toxicogenomics Technologies, and Past Patent Peer Review Committee Member of The Biojudiciary Project: A Jurist's Guide to 21st Century Biotechnology.